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510(k) Summary

Trade Name: Hoffmann® II Carbon Connecting Rods
Common Name: External Fixation Rod
Classification Name: Smooth or Threaded Metallic Bone Fixation
Fastener 888.3040

This submission describes a Carbon Fiber Composite Connecting Rod intended to be used with the components of the Hoffmann® II External Fixation System for the stabilization of open and/or unstable fractures where soft tissue injury precludes the use of other fracture treatments.

The rod is designed to provide a connecting element for the clamps in an external fixation frame. It is manufactured from a carbon fiber reinforced epoxy resin.

Equivalency of this device is based on similarities in intended use, materials, design and operational principles to the Hoffmann® Stainless Steel Rods, The Hoffmann® II Aluminum Rods, the Synthes Carbon Fiber Rods and the Carbon Tubes of The Monotube External Fixation System.

The Hoffmann® II Carbon Connecting Rods, the Synthes Carbon Fiber Rods and the Monotube Carbon Tubes are all manufactured from carbon fiber reinforced epoxy composites. All of these rods are designed to mate with external fixation clamps, intended to be used as connecting elements in pin fixation of fractures and are of a varying diameters and lengths to address different anatomic locations.

Testing of this device is presented in the submission. Testing was performed to determine static bending strength and stiffness, and torsional strength and stiffness. In each test the Hoffmann® II Carbon Rods were compared to the Hoffmann® stainless steel rods and/or Hoffmann® II aluminum rods.

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